BREAST HEALTH:

A Guide for Screening Programs

Texas Department of Health
Bureau of Women's Health
Breast and Cervical Cancer Control Program

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A Guide for Screening Programs of the Texas Department of Health
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Statement of Need

In Texas, 12,300 women will be diagnosed with breast cancer in 2001. Early detection can prolong long-term survival, yet almost 2,600 women will die from breast cancer in Texas this year. The burden will fall more heavily on certain populations such as low-income, minority, and rural women who have less access to care. With increased screening and early detection, Texas women may live longer with an improved quality of life.

In order to assure quality screening and diagnostic services for Texas women, the following protocol was developed by Texas Department of Health staff, work group members, and interested physicians and radiologists by adapting the protocol, Breast Health: A Guide for Health Departments, October 1994 from the North Carolina Breast and Cervical Cancer Control Program. Other sources include the National Cancer Institute, American Cancer Society, and the M.D. Anderson Cancer Center.

I. Screening for Breast Cancer

Definition: Screening is the attempt to detect unsuspected disease in asymptomatic clients.

Purpose: The purpose of breast screening is to improve survival by detecting breast cancer early.

Methods: The methods used for early detection and screening of breast cancer are clinical breast examination and mammography. According to the National Cancer Institute (NCI), screening with mammography combined with clinical breast examination has been noted to decrease mortality by 30 percent in women age 50 to 74. Mammography screening has not been shown to date to be as effective in decreasing mortality among younger women. This may be a result of the difficulty in interpreting the mammogram in denser breast tissue of younger women.

However, regular clinical breast examination, as well as mammography screening in high risk women age 40-49 is currently recommended by a majority of the medical community.

A. Client Education

Client teaching must be documented in the medical record. Teaching materials should be provided to the woman on clinical breast examination (CBE) and mammography. Materials should include but not be limited to:

- written and verbal information in a woman's primary language on CBE and mammography;
- recognizing the signs and symptoms of breast cancer and when to call the provider. Studies so far have not shown that breast self examination (BSE) alone reduces the number of deaths from breast cancer. Therefore, it should not be used in place of CBE and mammography;
- importance of adherence to recommended screening and re-screening guidelines;
- explanation of procedures (CBE, mammogram) and clinic flow; and
- limitations of screening:
    - Normal results on a screening examination do not necessarily indicate absence of disease;
    - No screening test is 100 percent accurate. Therefore, some cases of the disease may be inadvertently missed;
    - Normal results never rule out the later development of disease which is why ongoing regular screening is strongly recommended;
    - The detection of an abnormality does not mean it is cancerous. Approximately 20 percent of the women with abnormal screening results will, following further evaluation, be diagnosed with breast cancer; and
    - Women in their forties and older should be aware that a monthly breast self-examination is not a substitute for a regular scheduled screening mammogram and clinical breast examination by a health professional.

B. Clinical Examination

The examination should be conducted in a setting allowing for minimal distraction and adequate privacy for the woman. Examinations must be performed by a qualified clinician, such as a Registered Nurse, an Advanced Nurse Practitioner, a Certified Nurse Midwife, a Physician's Assistant, or a Physician. Examination gowns should be adjusted to minimize unnecessary exposure of the woman. Examinations should not be rushed; a complete CBE should last from 5 to 10 minutes. As part of the CBE, a breast health history should include:

$ Date and time intervals of previous mammograms;

$ Date and results of the last CBE;

$ Date and results of any previous breast surgery;

$ Date of last menstrual period;

$ History of medications (hormonal replacement therapy, oral contraceptives);

$ Risk factors for breast cancer (advancing age, personal history of breast cancer or breast biopsy results with moderate, severe, or atypical epithelial hyperplasia, or family history of first degree relative: mother, daughter or sister with premenopausal breast cancer), and;

$ Description of present breast symptoms, if any: lumps, pain or inflammation, nipple change or discharge, changes in shape, difference between breasts, cyclic tenderness, skin changes, lymph node enlargement.

Complete documentation of the CBE must be included in the clinical record.

- Frequency of clinical examination:
    - o **Ages 50 and older:** An annual CBE. Women age 70 and above should be screened unless otherwise indicated by health status.
    - o **Ages 40 - 49:** Annual CBE is recommended.

The BCCCP follows the NCI's recommendations of CBE.

- The CBE should include:

With the woman sitting: Inspection for asymmetry, abnormal superficial vascular patterns, dimpling, nipple retraction, and peau d'orange.

Palpation of axillary and supraclavicular/infraclavicular nodes. Note size, location, mobility, and consistency of nodes palpated.

With the woman supine: Inspection and palpation.

A recommended guide to performing the CBE is in Appendix A, "Procedures for Breast Assessment" from the M.D. Anderson Cancer Center Breast Screening Clinic.

- **All abnormal CBE findings that are suspicious for breast cancer must be referred for appropriate medical follow-up, regardless of what is noted on mammography.**

C. Mammography

Mammography screening guidelines are for women **without symptoms**. A physician or surgeon with expertise in breast problems should be consulted regarding a woman with breast symptoms **before** diagnostic tests are ordered.

- The BCCCP follows NCI recommendations for mammography screening:
    - **Ages 50 and older:** Women should be screened every year.
    - **Ages 40 to 49:** Women are encouraged to discuss, with a health professional, the advisability of breast cancer screening with mammography, taking into account family history of breast cancer and other risk factors. The BCCCP will screen women age 40-49 if they were enrolled in the program for breast cancer screening prior to October 1, 1994.
- Mammography facilities must be certified by the Food and Drug Administration (FDA) and the Texas Department of Health (TDH).
- Mammography results must be reported using the final assessment categories authorized under the Mammography Quality Reauthorization Act of 1998.
- The screening mammogram must be provided within the **60**-day period following the CBE. An exception of up to 90 days is allowed for providers using mobile mammography in rural areas.

- Previous mammography films should be sent to the referral mammography facility for comparison.

Note: The state program must be notified if the provider cannot meet the guidelines.

II. Follow-up Routine

Either an abnormal CBE or abnormal mammogram must generate a referral for appropriate follow-up. **A normal mammogram does not rule out cancer** if a woman has a mass on clinical breast examination and requires further diagnostic evaluation.

A. Minimum Expected Follow-up for Abnormal Screening Results

Follow-up of clinical breast examination results.

- Normal/benign: diagnostic referral must be based on whether mammogram results are abnormal

- Abnormal (suspicious for cancer): Follow-up must include referral for a mammogram with or without a additional views, ultrasound, and/or consultation with a surgeon or breast specialist (any two)

Follow-up of mammography result.

- Negative: diagnostic referral if clinical breast examination results are abnormal.

- Benign Negative: diagnostic referral if clinical breast examination results are abnormal.

- Probably Benign Finding-Short Interval Follow-up Suggested: radiologist must recommend the interval for the next screening or diagnostic examination **AND** diagnostic referral if clinical breast examination results are abnormal.

- Suspicious Abnormality, Biopsy Should Be Considered: follow-up must include a consultation with surgeon or breast specialist **AND** additional views, ultrasound, or biopsy.

- Highly Suggestive of Malignancy-Appropriate Action Should Be Taken: follow-up must include referral for consultation with surgeon or breast specialist with tissue sampling (biopsy).

Note: This is the expected minimum follow-up. More procedures or examinations may be necessary to clarify screening examination results and to obtain a final diagnosis.

The health provider must **initiate** attempts to notify a woman regarding her abnormal **screening** result and the implications of the breast cancer screening examination within five (5) working days after **receipt** of the abnormal result. For abnormal **diagnostic** results, an attempt to notify the woman must be made within two (2) working days after receipt of the abnormal finding. Information given to the woman should include:

- the nature of suspected disease;
- the need for further testing before treatment;
- a choice (if available) of appropriate referrals for definitive diagnostic procedures;
- an explanation that it is her responsibility to obtain follow-up care; and
- the opportunity to discuss her needs, including financial concerns, in regard to obtaining follow-up care.

The health provider must attempt to notify the woman and document those attempts in the medical record. The last attempt must be by certified mail. After three unsuccessful attempts to notify a woman with abnormal **screening** results, she may be considered "lost to follow-up". For abnormal **diagnostic** results, if contact is not made within two (2) working days, the provider must develop a plan of action based on the severity of the results.

B. Professional Consultations for Screening Follow-up

Referrals for follow-up of screening results must be made to physicians who have a recognized expedite in managing breast problems. Consultations must involve direct examination of the woman needing follow-up. A radiologist reading "outside" films or other imaging reports for the purpose of a second opinion without direct examination of the woman cannot be considered a professional consultation.

Nurses, midwives, nurse practitioners, physician assistants, and primary care physicians do **NOT** qualify as breast specialists. Radiologists and obstetricians and gynecologists may be considered breast specialists depending on the focus of their practice.

A consultation can only be performed by a clinician who did not perform the original screening examination.

III. Clinical Management of Abnormal Findings

Purpose: To determine the nature of breast disease with diagnostic procedures and pathologic confirmation.

A. The Palpable Mass

1. Solitary well-defined, palpable mass

Women with discrete solid masses must be referred to a surgeon or a physician with expertise in breast problems. A diagnostic mammogram or ultrasound may be ordered by the physician to define characteristics of the mass and, primarily, to look for similar lesions in either breast that are non-palpable.

Fine needle aspiration (FNA) or biopsy is an appropriate extension of evaluation of a palpable mass. Negative findings from Fine Needle Aspiration in the presence of a suspicious mass do not preclude further diagnostic biopsy, as the false-negative rate may be as high as 15-20 percent. Any mass remaining after aspiration of a cyst should be excised or biopsied.

Most masses are removed regardless of the woman's age. This advice applies not only to lesions thought to be suspicious of cancer but also to lesions felt to be benign. If a lesion is benign on mammography and FNA/biopsy, a woman, in consultation with her physician, may decide to have the mass removed. For some women, if a mass is not removed, it may cause continued concern and anxiety. For others, they may choose to monitor a benign-appearing mass.

A variety of symptoms perceived as “masses” by many women are in fact benign or functional in nature, and are not considered a palpable mass by the clinician. The provider may feel this area only as slightly lobulated breast tissue, (particularly premenstrually) an area of diffuse, poorly defined thickening that may or may not be matched in the opposite breast, or an area of irregularity or prominence such as nodular breast tissue. If there is any sense of concern or anxiety on the woman's part, it is good medical practice to advise the woman to return every one or two months for re-examination until she is convinced of the benign or functional nature of the changes. Menstruating women should be scheduled to return between the menstrual cycle (immediately after the menses are complete).

If there is significant doubt about the nature of the non-discrete mass, the physician may order an ultrasound and an FNA to obtain specific cellular

information. **One must remember that a negative FNA does not exclude cancer.**

The presence of discomfort and pain is not a reason to assume that the lesion is benign. While most painful or tender areas in the breast are functional in nature, caution should be exercised not to over-interpret the benign implication of this symptom.

2. Cysts

A palpable mass suspected to be a cyst should be evaluated by a physician and confirmed by FNA. If the primary care physician does not routinely perform aspirations, referral to a surgeon is appropriate. If a cyst is aspirated, the client should be re-examined for cyst recurrence at approximately six to eight weeks. Rapid recurrence of a cyst after aspiration should generate a surgical referral.

The ultrasound is most useful if there is a non-palpable abnormality detected on a mammogram. The ultrasound can then determine if the lesion is cystic or if it is solid and needs to be biopsied.

If the woman is over age 40 and has a palpable mass, the physician may obtain a mammogram prior to the cyst aspiration. A cyst aspiration can make interpretation of mammographic films difficult, particularly if a hematoma develops following the procedure.

If the mass does not disappear completely with aspiration or if the aspirated fluid is grossly bloody, the fluid should be sent for cytologic analysis and the woman should be referred to a surgeon. Cyst fluid does not otherwise need to be analyzed.

3. Vague Thickening or Nodularity Not Suspicious of Cancer

For premenopausal women, re-examine at mid-cycle after one or two menstrual cycles. If a localized area remains abnormal after repeated examinations, refer to a physician or surgeon with expertise in breast problems.

Questionable findings in post-menopausal women, including those post-menopausal women on estrogen replacement, should be referred to a physician or surgeon for consideration of FNA or biopsy. The role of FNA in this setting has not been completely established and referral to a surgeon is preferred.

B. Nipple Discharge or Skin Changes

The nature of the nipple discharge should be defined by a careful history. A woman with a spontaneous, unilateral clear, serous or bloody discharge should be referred to a radiologist. Cytologic analysis (Pap smear) of nipple discharges is rarely useful and should not be performed.

Bilateral multiple duct discharge is almost always benign, but should be referred to a physician. Medical work-up of galactorrhea may be appropriate for profuse, persistent milky discharge, but pituitary adenomas are rare.

Women with any skin breakdown on the nipple-areola complex should be referred to a physician or surgeon. Biopsy of the nipple may be indicated to differentiate eczema of the nipple from Paget's disease (cancer) of the nipple.

C. Breast Pain

If the physical examination and mammogram are negative, the most likely diagnosis is fibrocystic or functional changes. An explanation of the role of hormonal cycling will reassure most women. A trial of non-narcotic analgesics such as acetaminophen, aspirin or ibuprofen and the use of a brassiere, which provides good support, or the use of a heating pad or ice are suggested. Maneuvers such as elimination of caffeine, chocolate, or salt from the diet have not been found to be beneficial in scientific studies. However, some women report improvement in cyclical pain with reduction of caffeine and this may be suggested. Refer to a physician or surgeon if there is persistence of localized pain not responsive to conservative measures.

D. Non-palpable Masses Found on Mammography

There are six classifications established by the MQRA to record mammogram results:

- Negative
- Benign
- Probably Benign
- Suspicious
- Highly Suggestive of Malignancy, and
- Incomplete

A result of "suspicious" or "highly suggestive of malignancy" always requires a referral to a physician who is experienced in breast evaluation.

For suspicious abnormalities and findings highly suggestive of malignancy, always refer to a physician or surgeon who is experienced in breast evaluation.

In a screening setting, an indeterminate or incomplete assessment may be reported. Additional evaluation by a physician is then recommended before a final opinion can be rendered. An incomplete assessment always requires further follow-up on the part of the woman and the health professional who is responsible for follow-up.

1. Cysts

Non-palpable cysts detected by mammography and confirmed by ultrasound as simple cysts (i.e., without debris or ragged walls) need not be aspirated except for relief of pain. A non-palpable presumed cyst found to have suspicious characteristics by ultrasound should be subjected to directed biopsy or aspirated with sonographic guidance. The primary role of ultrasound is to distinguish the nature of a non-palpable lesion (cystic vs. solid) found on the mammogram.

2. Masses

A decision as to what form of evaluation or biopsy is most appropriate for any given non-palpable lesion that is discovered by mammography or ultrasound should be made by a surgeon in consultation with the radiologist. Options for non-palpable lesions include: mammographic or ultrasound-guided FNA, stereotactic core needle aspiration or biopsy, large core biopsy or open surgical biopsy.

IV. Special Considerations

A. Pregnant or Lactating Women with Breast Masses

Approximately one in 2,000 pregnant or lactating women have breast cancer and physical diagnosis of breast cancer may be extremely difficult in these situations. It is important to refer such women to a physician or surgeon with expertise in breast problems.

B. Difficult Breast Examinations, which may Require Surgical Referral for Evaluation

A woman could have an extremely difficult clinical examination and may need additional evaluation. This may include:

- A woman with post-reduction mammoplasty
- A woman with extremely large or dense multinodular breasts
- A woman who has had multiple biopsies with multiple scars producing a difficult examination
- A woman with breast implants

C. Breast Cancer Symptoms in Men

Male breast cancer is rare. One percent of all breast cancers reported are in men. Breast cancer in men may present with all the same signs and symptoms of breast cancer in women. However, the most common symptom is a palpable mass located directly behind the nipple. Masses in men are typically not tender or painful. Tenderness is usually associated with gynecomastia (excessive development of male mammary glands). Temporary gynecomastia often accompanies normal puberty, or may be caused by various drugs, testicular or chest cancer and cirrhosis. Breast cancer in adolescent males is extremely rare.

A frequently used procedure for diagnosing male breast cancer is the chest X-ray. Mammography is not normally performed on men because of limited breast tissue. The exception is obese men with large breasts or with gynecomastia. Men that present with breast cancer symptoms should be referred for diagnostic evaluation.

V. Use of Ultrasound in Screening Programs

Breast ultrasound (sonography or sonogram) has been in use for over 20 years. Because ultrasound offers many beneficial alternatives to mammography (no ionizing radiation, noninvasive and high client acceptability) it was envisioned as an early detection tool for breast cancer. However, ultrasound as a screening tool has not shown to reduce mortality. Ultrasound studies have reported that the procedure failed to detect over 90 percent of cancers that were less than one centimeter in diameter. **Therefore, ultrasound as a routine screening examination for asymptomatic clients is not recommended or reimbursed by the Breast and Cervical Cancer Control Program in Texas.**

While ultrasound is not considered a screening tool, it does have a place along with other evaluator tests in helping to diagnose breast problems detected during screening

examinations. Ultrasound is valuable in differentiating cystic from solid masses and as a guide for fine needle aspiration or placement of biopsy needles. The following are recommended guidelines for the use of breast ultrasonography in obtaining additional information on breast abnormalities and problems.

A. Women Age 30 or Younger

Women who present with breast symptoms (palpable mass, dimpling, puckering, nipple discharge) and are age 30 or younger may be directly referred for ultrasound. Breast abnormalities in this age group have a high probability of being benign and mammography may not detect abnormalities because of higher breast tissue density usually found in younger women.

B. Women Age 30 and Older

Palpable Mass

Women older than 30 who present with a palpable mass must be referred for an imaging evaluation that should include a diagnostic mammogram and/or ultrasonography based on the characteristics of the mass. If the diagnostic mammogram indicates a mass, a radiologist may refer the woman for ultrasound. The lesion may be cystic and can be aspirated at the time of the ultrasound if the cyst is causing pain and/or if the woman requests aspiration. Ultrasound can differentiate between cystic and solid masses, but not between benign versus malignant solid masses. Therefore, any woman who has a solid mass on ultrasound must be referred to a breast specialist or surgeon for possible biopsy as appropriate.

Non-Palpable Mass Detected on Mammography

Women age 30 or older who have a normal clinical breast examination but have an abnormal screening mammogram may be referred for either ultrasound or additional views based on the mammogram findings. If the mammogram results are Assessment Incomplete, the radiologist may refer the woman to ultrasound for further evaluation. If the mass is not clearly viewed on mammography or has definite irregular, microlobulated, ill-defined or spiculated margins or calcifications, a radiologist should refer the woman for additional views (if not already done) or a biopsy.

APPENDIX A

PROCEDURE FOR BREAST ASSESSMENT

"PROCEDURE FOR BREAST ASSESSMENT" FROM THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER BREAST SCREENING CLINIC

I Clinician inspects the breast, nipples, areolae, and chest wall

A. With the woman in a sitting position with her hands:

- relaxing in her lap or at her sides;
- pressing on her hips to contract pectoral muscles; and
- pressing against the back of her head with her chest flexed;
- on clinician's shoulders for support, leaning forward.

B. The following findings will be noted:

- asymmetry
- prominent unilateral veins
- discolorations (erythema or ecchymosis)
- peau d'orange
- dimpling, puckering, retraction of skin or areolae
- fixed inversion of nipple(s)
- crusting or erosion of the nipple(s) or areolae
- previous sites of surgical incisions

II Clinician palpates the supraclavicular and infraclavicular areas, chest wall, breasts, nipples, areola and bilateral axillae:

A. With the woman in a sitting position, the clinician:

- palpates the woman's axillae while supporting the elbow;
- palpates the supraclavicular and infraclavicular areas;
- "sweeps" hands over the woman's chest wall from clavicle to nipple; and
- bimanually examines the breast using the sandwich technique.

B. With the woman in a supine position with her hands behind her head, the clinician:

- palpates the woman's breasts including the axillary tail; and
- palpates beneath the areolae and nipples.

C. The following findings will be noted in the chart:

- overall consistency, distinct masses, and/or thickening;
- enlarged lymph nodes;
- areas of tenderness; and
- changes from previous examinations.

III For a woman post-mastectomy, the clinician:

- sweeps hand over the woman's chest wall on the affected side;
- gives particular attention to the mastectomy site and surrounding area;
- examines supraclavicular nodes and axillary area
- feels along ribs; and
- examines opposite side of chest following the previous steps 1 and 2

IV Clinician documents physical findings of the clinical breast examination (CBE) in medical record.

V All abnormal CBE findings will be referred for appropriate medical follow-up. A diagnostic mammogram rather than screening mammogram will be ordered by a physician or surgeon with expertise in diagnosis of breast problems.

APPENDIX B

GLOSSARY

GLOSSARY

Accessory breast tissue: An uncommon finding of additional breast tissue located in the axillary area. Because this area is not usually imaged clearly, women with this condition often require an extra view.

Adenoma: A well-circumscribed benign tumor of glandular tissue that can compress adjacent tissue as it grows in size; usually stays contained or does not "invade".

Adjuvant therapy: Treatment that is given in addition to the primary treatment. This is generally chemotherapy or hormonal therapy for clients with breast cancer after surgery.

Biopsy: The removal of a sample of tissue that is examined under the microscope to see if cancer cells are present. An *excisional biopsy* is surgery to remove an entire lump. An *incisional biopsy*, which is less commonly performed for breast tumors, removes part of the tumor. Removing tissue or fluid with a needle is called needle biopsy or aspiration.

Calcifications: Common finding in breast tissue and seen on mammography. A change in pattern, quantity or shape may indicate pathology.

Comparison films: By comparing present mammography films to past films, the radiologist is able to detect subtle changes that might otherwise be missed.

Compression artifacts: With breasts that are difficult to position or compress in an even pattern, overlying tissue can falsely appear to be abnormal. Extra views are required to complete the mammogram.

Cyst: A round, smooth, fluid-filled sac. A breast cyst often fluctuates in size with the menstrual cycle.

Dense tissue: The breast is composed of two types of tissue: fat and fibroglandular. Fibroglandular tissue is the denser of the two. Tumors and normal tissue are easier to distinguish in mammographic images taken through fat tissue.

Duct: A structure in the breast through which milk passes from the glands to the nipple.

Duct ectasia: A benign change where the ducts become dilated and retain secretions. This often leads to nipple discharge and can result in a lump in the nipple area or nipple retraction. This is not considered an increased risk for breast cancer.

Ductal carcinoma in situ: Breast cancer confined to the breast ducts; often shows micro-calcification on the mammogram.

Fat necrosis: A benign breast change where a firm, irregular mass forms as a result of trauma to the fatty tissue; the mass may appear years after the trauma. The injury causes the fat in the breast to become inflamed and form round, firm lumps, which may or may not be painful. The skin around them may appear red or bruised.

Fibroadenoma: Benign, usually painless masses most common in women in their 20's and 30's and seen more frequently in African American women. They are firm, rubbery, movable, and often rounded.

Fibrocystic changes: A non-specific term referring to a common condition of the breast. The condition is not cancer, but a benign change in the breast tissue due to cyclical hormone stimulation. These lumps or cysts are fluid-filled sacs that often enlarge and become tender just before the menstrual period. Cystic changes are most prominent in women age 35 to 50 years old. Both breasts are usually involved, and multiple cysts of many sizes are common.

Hormonal therapy: Women whose breast cancer is hormone sensitive may benefit by adjuvant anti-estrogen therapy. This drug is called tamoxifen. It is especially effective in post-menopausal women; it is taken orally and has mild side effects. The concern regarding prolonged use is an increased incidence of uterine cancer.

Incidence: The number of cases of illness commencing during a given period in a specified population. More generally, the number of new cases of a disease in a defined population, within a specified period of time.

Inflammatory breast cancer: A special class of cancer that is rare. The breast looks as if it is inflamed because of its red appearance and warmth. The skin shows signs of ridges and wheals or may have a pitted appearance. It tends to spread quickly.

In-situ: Pre-invasive stage of a malignant tumor. A breast change where highly atypical cells are localized and confined to the ducts or lobules; they have not invaded surrounding breast tissue.

Lobe: A part of the breast; each breast contains 15 to 20 lobes.

Lobule: A subdivision of the lobes of the breast.

Lumpectomy: Removal of a malignant lump and a small amount of normal breast tissue around it. Always followed by radiation therapy.

Modified radical mastectomy: Removes the breast, the lymph nodes under the arm, and the lining over the chest muscles (but leaves the muscles). This is currently the most common surgery for breast cancer in the U.S.

Peau d' orange: A dimpled condition of the skin, resembling that of an orange.

Total or simple mastectomy: Removes the breast and, sometimes, the lymph nodes closest to the breast.

Partial or segmental mastectomy: Removes the tumor, some of the normal breast tissue around it, and the lining over the chest muscle below the tumor. Usually some of the axillary lymph nodes are removed. In most cases, radiation therapy follows the surgery.

Radical mastectomy (also called the "Halstead radical"): Removes the breast, chest muscles, all of the lymph nodes under the arm, and some additional fat and skin. For many years, this operation was the standard procedure.

Negative predictive value: The proportion of cases with a negative test that are found by diagnostic evaluation to not have the disease in question. The higher the negative predictive value, the lower the number of false-negative results.

Positive predictive value: The proportion of cases with a positive test that are found by diagnostic evaluation to have the disease in question. The higher the positive predictive value, the lower the number of false-positive results. (e.g. 10 cancers out of 100 abnormal cases equals a positive predictive value of 10%).

Prevalence: The number of instances of a given disease (e.g. breast cancer) in a given population at a designated time.

Radiation therapy: Treatment used following lumpectomy, segmental or partial mastectomy. The rationale for using radiation is to eradicate other cancer cells that may be present in the remaining breast and decrease the chance for local breast cancer recurrence.

Screening: The presumptive identification of unrecognized disease.

Sensitivity: Sensitivity is the proportion of truly diseased persons in the screened population who are identified as diseased by a screening test. Sensitivity is a measure of the probability that any given case will be identified by the test.

Specificity: Specificity is the proportion of truly non-diseased persons who are identified as non-diseased by the screening test. It is a measure of the probability of correctly identifying a non-diseased person with a screening test.

Stage: A distinct phase in the course of a disease. Stages of cancer are typically defined by containment of spread of the tumor: in situ, localized, regional or distant spread.
Stage I: The cancer is no bigger that 2 centimeters (about 1 inch) and has not spread outside the breast.

Stage II: The cancer is no bigger than 2 centimeters, but has spread to the lymph nodes under the arm; or the cancer is between 2 and 5 centimeters and may or may have not spread to the lymph nodes; or the cancer is bigger than 5 centimeters, but has not spread to the axillary nodes.

Stage III: (IIIa) The cancer is bigger than 5 centimeters and has spread to the lymph nodes or is smaller than 5 centimeters, but has spread into the lymph nodes and other structures attached to them. (IIIb) The cancer has spread to tissues near the breast (chest wall, including the ribs and muscles in the chest).

Stage IV: The cancer has spread to other organs of the body, most often the bones, lungs, liver or brain.

Stereotactic biopsy: An x-ray guided method to localize and sample suspicious lesions discovered on mammography. It is particularly helpful in sampling small, non-palpable breast lesions using fine-needle aspiration for cytology or core-needle biopsy for histology.

Synchronous: A lesion or mass that appears at the same time as the original mass that is detected by clinical breast exam or mammogram.

Ultrasound: High-frequency sound waves forming a pattern of echoes that are electronically translated into a visual image. Can help distinguish between solid masses and cysts.

APPENDIX C

BREAST IMAGING OVERALL ASSESSMENT OF FINDINGS CLASSIFICATIONS

BREAST IMAGING FINAL CLASSIFICATIONS FOR MAMMOGRAM ASSESSMENT

I. Negative:

There is nothing to comment on. The breasts are symmetrical and no masses, architectural disturbances, or suspicious calcifications are present.

II. Benign:

This is also a negative mammogram, but the interpreter may wish to describe a finding. Involuting, calcified fibroadenomas, multiple secretory calcifications, fat containing lesions such as oil cysts, lipomas, galactoceles, and mixed density hamartomas all have characteristic appearances, and may be labeled with confidence. The interpreter might wish to describe intramammary lymph nodes, implants, etc. while still concluding that there is no mammographic evidence of malignancy.

III. Probably Benign:

A finding placed in this category should have a very high probability of being benign. It is not expected to change over the follow-up interval, but the radiologist would prefer to establish its stability. Data are becoming available that shed light on the efficacy of short interval follow-up. At the present time, most approaches are intuitive. These will likely undergo future modification as more data accrue as to the validity of an approach, the interval required, and the type of findings that should be followed.

IV. Suspicious:

These are lesions that do not have the characteristic morphologies of breast cancer but have a definite probability of being malignant. The radiologist has sufficient concern to urge a biopsy. If possible, the relevant probabilities should be cited so that the woman and her physician can make the decision on the ultimate course of action.

V. Highly Suggestive of Malignancy-Appropriate Action Should Be Taken:

These lesions have a high probability of being cancer. Appropriate action should be taken.

APPENDIX D

CLINICIAN QUALIFICATIONS FOR PERFORMING BREAST EXAMINATIONS

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I. Clinicians qualified to do a Clinical Breast Examination:

A. Registered Nurse: A Registered Nurse who has received specialized training as part of a recognized program in breast exams beyond nursing school may perform the CBE.

B. Advanced Nurse Practitioner

C. Registered Nurse-Midwife

D. Physician's Assistant

E. Physician

Clinics must be able to provide evidence that staff are adequately trained to perform the Clinical Breast Examination.